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EXAMINER	
YOUNG, SHAWQUIA	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
03/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,164	MERCE VIDAL ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *14-16,19-44 and 47-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17,18,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/27/06, 4/17/06, 4/20/06, 5/9/07, 9/21/07, 10/30/07.

DETAILED ACTION

Claims 1-72 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/EP04/08512, filed on July 29, 2004 and claims benefit of Foreign Application SPAIN P 200301807, filed on July 30, 2003.

II. *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on January 27, 2006, April 17, 2006, April 20, 2006, May 9, 2007, September 21, 2007 and October 30, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election of species N-[1-(2-dimethylaminoethyl)-1H-indole-4-yl]naphthalene-2-sulfonamide with traverse in the reply filed on October 29, 2008 is acknowledged. The traversal is on the ground(s) that: (1) that the Office has failed to meet the burden necessary in order to sustain the restriction requirement.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be

independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that the reference cited by the Examiner showing that Applicants' special technical feature does not provide a contribution over the prior art does not anticipate or render obvious Applicants' compounds as claimed. However, the Examiner wants to point out that the purpose of citing the reference was to show Applicants that the special technical feature in the claims does not provide a contribution over the prior art. The Examiner wants to make clear that Applicants special technical feature does not include the variables shown in formula Ia since the each variables has its own extensive definition. The Examiner has met the burden of maintaining the restriction requirement, thus the restriction requirement is deemed proper and made final.

The Examiner also wants to point out that Applicants' claims are Markush-type claims. Different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The inventions are classified into classes 514, 544, 546 and 548. However, each Class 514, 544, 546 and 548 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety.

Applicants have elected a species and as stated in the Restriction Requirement,

the Examiner will group the species. However, the Examiner wants to make clear that the group will not include all of the subject matter claimed in claim 1 because as discussed in the paragraph above Applicants' claim 1 alone is classified into various classes such as 544, 546, 548, etc. Applicants' elected group is as follows: Claims 1-13, 17, 18, 45 and 46 are drawn to a sulfonamide compound of formula (Ia) wherein R^1 is as defined in claim 1; R^2, R^3, R^5, R^6 and R^7 is as defined in claim 1; R^4 is as defined in claim 1; R^8 and R^9 are as defined in claim 1; A is an optionally at leas mono-substituted phenyl or napthyl ring; and n is 0,1,2,3 or 4.

Subject matter not encompassed by the above elected Group are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

IV. Rejections

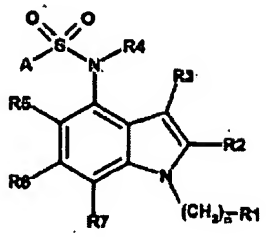
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 -7 are rejected under 35 U.S.C. 102(b) as being anticipated by *Semmelheck, et al.* (RN 148773-85-7, CAPLUS). The instant invention claims a product

with the formula  wherein R^1 is as defined in claim 1; R^2, R^3, R^5, R^6 and R^7 is as defined in claim 1; R^4 is as defined in claim 1; R^8 and R^9 are as defined in claim 1; A is an optionally at leas mono-substituted phenyl or napthyl ring; and n is 0,1,2,3 or 4.

The *Semmelheck, et al.* reference teaches indole derivatives such as N-[7-(1-cyano-1,5-dimethyl-4-hexen-1-yl)-1-(phenylmethyl)-1H-indol-4-yl]-N,4-dimethyl-benzenesulfonamide. This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

35 USC § 103 - OBVIOUSNESS REJECTION

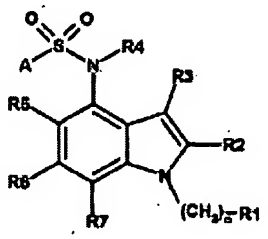
The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). *See Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

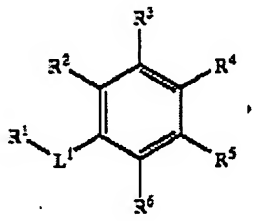
1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 17, 18, 45 and 46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Li, et al.* (US Patent 6,521,658). Applicants claim a product with the formula  wherein R^1 is as defined in claim 1; R^2, R^3, R^5, R^6 and R^7 is as defined in claim 1; R^4 is as defined in claim 1; R^8 and R^9 are as defined in claim 1; A is an optionally at leas mono-substituted phenyl or napthyl ring; and n is 0,1,2,3 or 4.

The Scope and Content of the Prior Art (MPEP §2141.01)

Li, et al. teaches indole derivatives that are cell proliferation inhibitors. The invention is represented by the general formula:



wherein all of the variables are clearly defined at columns 1-4 of the reference. Specifically, the substituents of R^1 are selected from the group consisting of oxo, azido,

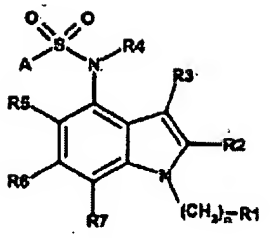
carboxy, carboxaldehyde, cyano, halo, hydroxyl, nitro, perfluoroalkyl, perfluoroalkoxy, alkyl, alkenyl, alkynyl, alkanoyloxy, alkoxycarbonyl, cylcoalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, alkanoyl, alkoxy, cycloalkoxy, aryloxy, heteroaryloxy, thioalkoxy, alkylsulfinyl, alkyl sulfonyl, an amine (-NR8R9) and -SO2NR8R9 (See column 3, lines 9-57).

The reference teaches specific compounds such as 3,4, 5-trimethoxy-N-(1-methyl-1H-indol-4-yl)benzenesulfonamide (example 29C, column 30, lines 33-34).

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Li, et al.* and the instant invention is that there is homologous subject matter. Not all of the substituents are taught, however there is overlap between the substituents disclosed especially in view of the examples taught by the prior art. The instant compounds have a substituent at the nitrogen atom of the indole ring which is $(CH_2)_n$-R1 wherein R1 is selected from an amine (-NR8R9) or a saturated or unsaturated cycloaliphatic radical and n is 0, 1, 2, 3 or 4 and prior art teaches a specific indol-4-sulfonamide compound wherein the nitrogen atom is substitued by a methyl group. However, the prior art broadly teaches that the heteroaryl group (i.e. indole) can be subsituted with 1-5 substituents selected from a group including cycloalkyl, cycloalkenyl, an amine, etc.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)



Applicants are claiming a a product with the formula

wherein R^1 is as defined in claim 1; R^2, R^3, R^5, R^6 and R^7 is as defined in claim 1; R^4 is as defined in claim 1; R^8 and R^9 are as defined in claim 1; A is an optionally at leas mono-substituted phenyl or napthyl ring; and n is 0,1,2,3 or 4. The prior art reference of *Li, et al.* teaches a similar compound wherein the substituents at the nitrogen atom is methyl but broadly teaches that the heteroaryl group (i.e. indole) can be substituted with alkyl, cycloalkyl, cycloalkenyl, an amine, etc. The prior art teaches the specific compound 3,4,5-trimethoxy-N-(1-methyl-1H-indol-4-yl) benzenesulfonamide (example 29 C, column 30).

Since the prior art reference teaches a specific compound with a methyl substituted at nitrogen atom of the indole ring and broadly teaches numerous substituents that could be substituents on the indole ring, it would be obvious to prepare similar indol-4-sulfonamide compounds wherein the substituents are cycloalkyl, cycloalkenyl, an amine, etc. based on the teachings of the prior art with a reasonable expectation of success. Specifically, indol-4-sulfonamide compounds with cycloalkyl ring, cycloalkenyl, an amine group at the 1-position are considered obvious since these substituents were taught by the prior art. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare indol-4-sulfonamide derivatives based on the teachings of the preferred

embodiments in the prior art. A strong prima facie obviousness has been established.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 17, 18, 45 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18, 19, 46, 47 and 74-93 of copending Application No. 10/566,094; claims . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-5, 9, 10, 15-19, 21-25 and 30 provide products which are obvious variants with the copending application's claimed products and provide species in the instant claims which render obvious the copending application's claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13, 17, 18, 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18, 46 and 75-91 of US Patent 7,414,070 and 1-18, 46 and 74-100 of US Patent 7,462,640. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-13, 17, 18, 45 and 46 provide products which are obvious variants with the copending patent's claimed products and provide species in the instant claims which are obvious over the copending patent's claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 17, 18, 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "substituted" found in all of the variables in the pending claims renders the products indefinite as the term "substituted" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula Ia that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the claims to include the substituents that are included in the term "substituted" which are supported by the specification in claims 1-13, 17, 18, 45 and 46.

Claims 1-13, 17, 18, 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the limitation "a saturated or unsaturated, optionally at least mono-substituted cycloaliphatic radical, which may contain at least one heteroatom as a ring member and/or may be condensed....." in variable R^1 is not clearly defined in the claims or the specification so

that one of ordinary skill in the art would know the metes and/or bounds of the limitation. Therefore, the limitation is including additional subject matter in the compounds of the formula Ia that is not described in the instant specification and is not particularly pointed out or distinctly claimed.

Claims 18 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, various genus diseases listed in claim 18 and 46 such as gastrointestinal tract disorders, disorders of the central nervous system, panic disorders, cognitive memory disorders, neurodegenerative disorders, etc. have not been clearly defined in the specification to know all of the diseases or disorders that are included by each of the genus diseases listed.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 17, 18, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (Ia) or physiologically acceptable salts of said compound does not reasonably provide enablement for a **solvate** of a compound of formula (Ia). The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a compound of formula (Ia) or one of its stereoisomers, its racemate or a salt. There is no teaching of solvates of the compounds of Formula I in the specification.

The state of the prior art and predictability or lack thereof in the art

It is the state of the prior art that the term "solvate" found in the claims is defined as a compound formed by solvation (the combination of solvent molecules with molecules or ions of the solute. It has been estimated that approximately one-third of

the pharmaceutically active substances are capable of forming crystalline hydrates. Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compound (See *Vippagunta, et al.*)

The scope of "solvate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active *in vivo*. Solvates and hydrates cannot always be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular hydrate or solvate.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what solvates are being included in the elected invention. The term "solvates" is discussed on page 39 of the specification and reads on the following:

> "The solvates, preferably the physiologically acceptable solvates, more preferably hydrates...".

The breadth of the claims

The breadth of the claims is a compound of formula (Ia) or one of its stereoisomers, its racemate or a salt or a corresponding solvate thereof.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to what compounds form solvates with which solvents.

The level of skill in the art is high without showing or guidance as to how to make solvates of a compound of formula (I) it would require undue experimentation to figure out the solvents, temperatures and reaction times that would provide solvates of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the term "solvates".

Claims 18 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

Applicants are claiming a medicament for 5-HT6 receptor regulation, for the prophylaxiss and/or treatment of various disorders or diseases listed in claims 18 and 46.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that neurodegenerative disorders, for example, remain highly unpredictable. Enablement for the scope of treating and preventing diseases such as type II diabetes, disorders of the central nervous system, panic disorders, neurodegenerative disorders, etc. is not present in the specification.

Furthermore, there is a vast range of causes for the problem and biochemical pathways that mediate neurodegenerative disorders, for example, that affect the various nervous systems. There is no common mechanism by which all, or even most, neurodegenerative disorders arise and one treatment cannot be used to treat all types

of neurodegenerative disorders.

Applicants' claims are therefore drawn to a medicament for preventing and/or treating Alzheimer's disease. It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease. (<URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html>.)

In addition, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents (*See* e.g., the Cecil Textbood of Medicine, 20th edition (1996), Vol. 2, page 1994).

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can be used to treat or control all diseases embraced by the claims is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating, controlling or preventing any or all conditions by administering the instant claimed compounds.

The breadth of the claims

The breadth of the claims is a medicament for preventing and/or treating all of the diseases or disorders listed in claims 18 and 46.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of

skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

V. Objections

Claim Objection-Non Elected Subject Matter

Claims 1-13, 17, 18, 45 and 46 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

Claim Objections

Claims 4-7, 11-13, 17, 18, 45 and 46 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 4-7, 11-13, 17, 18, 45 and 46 not been further treated on the merits.

VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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